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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,684	05/04/2006	Andreas Hefel	RBL0109-01	7978

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BAKER & DANIELS LLP
111 E. WAYNE STREET
SUITE 800
FORT WAYNE, IN 46802

EXAMINER	
ML, QIUWEN	
ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,684	HEFEL, ANDREAS	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-41* is/are pending in the application.

4a) Of the above claim(s) *25-27 and 29-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/4/06; 11/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 22-41 are pending.

Applicant's election of Group I, claims 22-30, and species antioxidant and co-Enzyme Q10, in the reply filed on 11/10/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 25-27, and 29-41 are withdrawn from further consideration as being drawn to nonelected invention groups and species.

Claims 22-24, and 28 are examined on the merits.

Specification/Abstract Objections

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, Applicant is required to delete "The invention relates to" on line 1 of the Abstract to be more clear and concise. The first letter of "a" in line 1 should be capitalized after the deletion.

Claim Objections

Claim 23 is objected to because of the following informalities: Claim 23 recites "HGH" in line 1. It is improper to recite the abbreviations in the claims, and Applicant is required to spell out the full name of the abbreviations.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-24, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is insufficient antecedent basis for the following limitations in the claims.

"for the increase" in claim 22, line 1;

"the nutrient-bio-availability" in claim 22, lines 1 and 4;

"the water" in claim 22, line 5;

"the from this obtained granulate" in claim 22, line 7;

"the embedded active substances" in claim 22, lines 7 and 8;

"the human or animal" in claim 22, line 8;

"the mentioned nutritional material" in claim 24, line 1;

"the mentioned antioxidants" in claim 28, line 1

"the co-enzyme Q10" in claim 28, line 2.

Claim 22 recites "a test person that wishes such an increase" in line 2, and metes and bounds of "a test person that wishes such an increase" are unclear as to the meaning of the subject matter".

Claim 22 recites "Procedure" in line 1, which is incorrect, "A procedure" should be used instead. Consequently, "Procedure" in claims 23, 24, and 28 (line 1) should be replaced with "The procedure".

Claim 23 (lines 1-2) recites parenthetical expression "(source somatotropin)". The metes and bounds of Claim 23 are rendered vague and indefinite by the parenthetical recitation of "(source somatotropin) because it is unclear as to whether the limitation is part of the instantly claimed subject matter.

Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22-24, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibata (EP 835654 A1), in view of Ron et al (US 5,122,367), and further in view of Shefer et al (US 2003/0195133).

Shibata teaches a method of producing a pharmaceutical preparation with sustained effect for oral administration of a pharmacologically active ingredient, which method comprises admixing a predetermined amount of said pharmacologically active ingredient with a predetermined amount of glucomannan (claim 4). Glucommannan is the chief polysaccharide present in the corms of a variety of Amorphophallus plants (thus a botanical matrix of a polysaccharide). The inventor noted that glucomannan makes a very viscous solution when dissolved in water and that glucomannan is not decomposed in the small intestine but is decomposed in the large intestine by Escherichia coli and loses its viscosity. The inventor then sought the possibility of properly delaying absorption of a drug in the small intestine both by suppressing conveyance of the drug though the small intestine in the direction to the anus and suppressing diffusion of the drug in the solution (thus slowly released for resorption by the human or animal digestive system), both making use of the viscosity of the solution. As a result, the inventor has found that when glucomannan is orally administered together with a drug, gradual absorption of the drug occurred over a prolonged time period (thus increase of the nutrient-bio-availability of vital substances) compared with the case without administration of glucomannan, and that there is no reduction of overall absorption of the drug (thus separated

from each other in their function) (page 2, lines 28-38). Thus, the present invention provides a pharmaceutical preparation with sustained effect for oral administration of a pharmacologically active ingredient comprising a mixture of said pharmacologically active ingredient and glucomannan (thus increase for improvement of wellbeing) (thus the embedded active substances are slowly released for resorption). In accordance with the present invention, the length of time during which the absorption of the pharmacologically active ingredient takes place may be conveniently controlled by simply adjusting the proportion of glucomannan to the amount of the active ingredient. Thus, the present invention allows sustainment of pharmacological effect of a variety of active ingredients orally administered to mammals including human (page 2, lines 38-44). Shibata further teaches the pharmaceutical preparation may be in any convenient form suitable to oral administration, such as a powder, granules, capsules, tablets, an aqueous preparation (page 3, lines 20-22).

Shibata does not teach HGH is embedded in galactomannan and or glucomannan; neither does Shibata teach the nutritional material comprises antioxidant coenzyme Q10.

Ron et al teach a simple polysaccharide such as sucrose is used both as a stabilizer, to hinder denaturation and to increase the thermal stability of the growth hormone, and to modulate the release rate of the growth hormone from the bioerodible controlled release device. The result is an increase in the duration of release of the peptide and a decrease in initial release rate, when compared to non-stabilized composition, which permits longer and more uniform therapeutic treatment, without aggregation of the growth hormone (col 1, lines 20-30).

Shefer et al teach controlled delivery composition (see Title). Shefer et al teach the controlled release system of the invention can also contain other antioxidants including those well known in the art. Representative antioxidants include vitamin E, tocopheryl acetate, betaglucan, and coenzyme Q10 [0136].

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to adopt the procedure of using the polysaccharide to modulate the release rate of the growth hormone from Ron et al since Ron et al teach it permits longer and more uniform therapeutic treatment. Since Glucommannan is the chief polysaccharide present in the corms of a variety of Amorphophallus plants, and it would have been obvious to adopt the procedure of using glucommannan to modulate the release rate of the growth hormone so as to increase the bioavailability of the hormone since Shibata teaches glucommannan has sustained effect for oral administration of a pharmacologically active ingredient.

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to adopt the procedure of using antioxidant coenzyme Q10 in the slowly released/control released system since Shefer et al teach the controlled release system of the invention can also contain antioxidants coenzyme Q10. Furthermore, since Shibata teaches galactomannan allows sustainment of pharmacological effect of a variety of active ingredients orally administered to mammals, one of ordinary skill in the art would have adopted the procedure of using glucomannan to sustain the pharmacological effect of antioxidant coenzyme Q10.

Since all the references yielded beneficial results in control released delivery system, one of ordinary skill in the art would have been motivated to make the modifications and combine the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/
Primary Examiner, Art Unit 1655